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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,867	11/17/2003	Jeffrey A. Hubbell	50320/002004	5598
21559	7590	06/28/2007	EXAMINER	
CLARK & ELBING LLP			WARE, DEBORAH K	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	
			1651	
			MAIL DATE	
			DELIVERY MODE	
			06/28/2007	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,867	<b>Applicant(s)</b> HUBBELL ET AL	
	<b>Examiner</b> Deborah K. Ware	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 59-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

Claims 59-69 are presented for examination on the merits.

### ***Response to Amendment and Declaration***

The amendment filed March 27, 2007, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of the claims of U.S. Patent No.

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5,626,863; 5,986,043; 5,567,435; and 5,410,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claimed composition and the patented claims is scope.

Claims are drawn to compositions comprising a protein or peptide within a biodegradable polymerized macromer.

The patented claims are drawn to compositions comprising a biologically active substance within a biodegradable polymerized macromer, of which may be a protein of which proteins can contain peptides.

The difference between them is simply scope and the patented claims would have made obvious the instant claims as the compositions are very similar. Thus, the claims are prima facie obvious over the cited prior art. Each of the newly cited patents teach that the biological active compound is a protein. These proteins can contain peptides. Thus, it would have been an obvious modification to select for a peptide in place of a protein. Also to vary the amount of protein or peptide to be contained by the composition in an amount of 5% by weight of the protein or peptide, as the case might be, is well within the purview of an ordinary artisan. The water soluble region, at least one degradable region which is hydrolyzable under in vivo conditions and polymerized end groups, that are separated by the degradable region are all required features of the patented claims. Also the water soluble region can be a polyester or PEG (polyethylene glycol), see the patented claims. Therefore, the patented claimed subject matter would have made obvious the claimed invention at the time it was made. In the absence of

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persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited patents.

### ***Response to Arguments***

Applicant's arguments filed March 27, 2007, have been fully considered but they are not persuasive. The argument that making and delivering macromers containing such high percentages of protein by weight (at least 5%) is not obvious, however, the claims are directed to a composition and not a method of making or method of delivering per se. Also with respect to Applicants' declaration which is a copy of one that was actually filed in case serial no. 09/118, 242, now U.S. patent 6,153,211 is, not deemed persuasive for the product because it was directed to method claims and not composition claims. To vary the percentage amount by weight of a biologically active substance is clearly within the guidance of one of ordinary skill in the art. The declaration also refers to bursting with a lysozyme which would be expected since the nature of the enzyme is to degrade its substrata. The instant claims are not directed to lysozyme but to a protein.

This is further supported when comparing lysozyme with the BSA as noted in the declaration. Thus, for the instantly claimed composition claims the declaration is not deemed persuasive. Also the argument that an "obvious to try" application of the prior art has been applied is noted, but the patented claims make obvious a composition as claimed because to vary the amount of protein or peptide to be contained by the composition in an amount of 5% by weight of the protein or peptide, as the case might be, is well within the purview of an ordinary artisan. The water soluble region, at least

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one degradable region which is hydrolyzable under in vivo conditions and polymerized end groups, that are separated by the degradable region are all required features of the patented claims which make the instant product claims obvious.

One of skill would have been led by the cited prior art to provide for the claimed composition. Therefore, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

One of skill would have expected successful results that the claimed composition would have desirable controlled release properties and Applicants admit that it is desirable maximizing loading of the macromer. Based upon the cited prior art and what was known before one of skill would have desired to control bursting and would have known how to control it too by selecting an appropriate biological load for the macromer. They would have been motivated to control bursting and would not have been led to not load macromers with biologically active components because of the desire recognized in the art to perform such loading of biologically active compounds. Further, any court decisions are based on other cases and not this one and hence the argument is not deemed persuasive.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

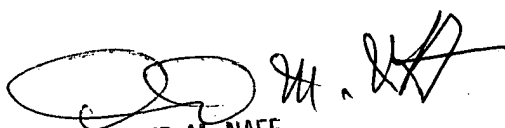
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware  
June 23, 2007



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128/657